World Health Organization

Trial Registration Data Set

Introduction

The Registry Platform has finalized the Trial Registration Data Set. In order to register a trial, Responsible Registrants must complete Items #3 to #20 for submission to a Primary or Associate Register. The previous list of 20 items will be acceptable for registration until further notice. The WHO encourages all registers to transition to the new data set as soon as possible.

The "form" on the next page is just an example to illustrate the data values, **and is NOT an interface for submitting data to the WHO or to any register**. Actual register submission interfaces will be different from this illustration. All entries can be in free text (i.e., do not have to be terms from a controlled vocabulary), although some registers may require or encourage coded entries. The Registry Platform is considering MeSH as the common vocabulary for any coding of register entries.

Please note that this Data Set applies only to interventional trials.

Registration Data Set (Version 1.0)

This WHO Trial Registration Data Set is now finalized. Specific implementation details remain to be resolved and will be codified in a guidance document that is being developed (e.g., specific pick list options, whether age criteria will be collected in structured form, etc). The "field value" column given below is just an example to illustrate the data fields, and does not reflect an actual interface for submitting data to the WHO or to any register. This Data Set will be reviewed in 2 years.

For a trial to be properly registered, all items must be recorded as applicable in a Primary Register. All entries should accurately reflect the study protocol. Entries can be in free text (i.e., do not have to be terms from a controlled vocabulary), although some registers may require or encourage coded entries. The Registry Platform is considering MeSH as the common vocabulary for coding Conditions, Interventions, and Primary Outcomes.

	Item	Field Value	Definition/Explanation
1	Primary Register and Trial ID #	[ ] Trial ID # [ ]	Name of Primary Register, and the unique ID number assigned by the Primary Register to this trial.
2	Date of Registration in Primary Register	[ ] [ ] [ ]	Date when trial was officially registered in the Primary Register YYYY/MM/DD.
3	Secondary ID#s	Issuing Authority [ ] ID Number [ ] Click to add more..	Other identifying numbers and issuing authorities besides the Primary Register, if any. Include the sponsor name and sponsor-issued trial number (e.g., protocol number) if available. Also include other trial registers that have issued an ID number to this trial. There is no limit on the number of Secondary ID numbers that can be provided.
	Source(s) of		Major source(s) of monetary or material

EXHIBIT 2

4	**Monetary or Material Support**	Name Click to add more...	support for the trial (e.g., funding agency, foundation, company).
5	**Primary Sponsor**	Name	The individual, organization, group or other legal person taking responsibility for securing the arrangements to initiate and/or manage a study (including arrangements to ensure that the study design meets appropriate standards and to ensure appropriate conduct and reporting). In commercial trials, the primary sponsor is normally the main applicant for regulatory authorization to begin the study. It may or may not be the main funder.
6	**Secondary Sponsor (s)**	Name Click to add more...	Additional individuals, organizations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship. A secondary sponsor may have agreed • to take on all the responsibilities of sponsorship jointly with the primary sponsor; or • to form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group; or • to act as the sponsor's legal representative in relation to some or all of the trial sites; or • to take responsibility for the accuracy of trial registration information submitted.
7	**Contact for Public Queries**	Email, telephone number, or address	Email address, telephone number, or postal address of the contact who will respond to general queries, including information about current recruitment status
8	**Contact for Scientific Queries**	Email, telephone number, or address Affiliation	Email address, telephone number, or postal address, and affiliation of the person to contact for scientific queries about the trial (e.g., principal investigator, medical director employed by the sponsor). For a multi-center study, enter the contact information for the lead Principal Investigator or overall scientific director.
9	**Public Title**		Title intended for the lay public in easily understood language.
10	**Scientific Title**	Acronym	Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available.
11	**Countries of Recruitment**		The countries from which participants will be, are intended to be, or have been recruited.
			Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error). If the study is conducted in

12	**Health Condition(s) or Problem(s) Studied**		healthy human volunteers belonging to the target population of the intervention (e.g., preventative or screening interventions), enter the particular health condition(s) or problem(s) being prevented. If the study is conducted in healthy human volunteers not belonging to the target population (e.g., a preliminary safety study), an appropriate keyword will be defined for users to select.
13	**Intervention(s)**	Intervention name(s) Other details (e.g., dose, duration, etc.) Click to add more experimental interventions Control Intervention name Other details of control (e.g., dose, duration, etc.) Click to add more control interventions	Enter the specific name of the intervention(s) and the comparator/control(s) being studied. Use the International Non-Proprietary Name if possible (not brand/trade names). For an unregistered drug, the generic name, chemical name, or company serial number is acceptable. If the intervention consists of several separate treatments, list them all in one line separated by commas (e.g., "low-fat diet, exercise") The control intervention(s) is/are the interventions against which the study intervention is evaluated (e.g., placebo, no treatment, active control). If an active control is used, be sure to enter in the name(s) of that intervention, or enter "placebo" or "no treatment" as applicable. For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc)
14	**Key Inclusion and Exclusion Criteria**	Inclusion Criteria Exclusion Criteria	Inclusion and exclusion criteria for participant selection, including age and sex
15	**Study Type**	Choose one	A single arm study is one in which all participants are given the same intervention. Trials in which participants are assigned to receive one of two or more interventions are NOT single arm studies. Crossover trials are NOT single arm studies. A trial is "randomized" if participants are assigned to intervention groups using a method based on chance (e.g., random number table, random computer-generated sequence, minimization, adaptive randomization).
16	**Date of First Enrollment**		Anticipated or actual date of enrollment of the first participant (YYYY/MM).
17	**Target Sample Size**		Number of participants that this trial plans to enroll.
			Recruitment status of this trial. • Pending: participants are not yet being recruited or enrolled at any site

18	**Recruitment Status**		• Active: participants are currently being recruited and enrolled • Temporary halt: there is a temporary halt in recruitment and enrollment • Closed: participants are no longer being recruited or enrolled
19	**Primary Outcome(s)**	Outcome Name Timepoints Click to add more outcomes	Outcomes are events, variables, or experiences that are measured because it is believed that they may be influenced by the intervention. The Primary Outcome should be the outcome used in sample size calculations, or the main outcome(s) used to determine the effects of the intervention(s) Enter the names of all primary outcomes in the trial as well as the pre-specified timepoint (s) of primary interest Be as specific as possible with the metric used (e.g., "% with Beck Depression Score > 10 "rather than just "depression") Examples: Outcome Name: all-cause mortality, Timepoints: 5 years; or Outcome Name: Mean Beck Depression Score, Timepoint: 18 weeks
20	**Key Secondary Outcomes**	Outcome Name Timepoints Click to add more outcomes	Secondary outcomes are events, variables, or experiences that are of secondary interest or that are measured at timepoints of secondary interest. A secondary outcome may involve the same event, variable, or experience as the primary outcome, but measured at timepoints other than those of primary interest (e.g., Primary outcome: all-cause mortality at 5 years; Secondary outcome: all-cause mortality at 1 year, 3 years), or may involve a different event, variable, or experience altogether (e.g., Primary outcome: all-cause mortality at 5 years; Secondary outcome: hospitalization rate at 5 years). Enter the name and timepoint(s) for all secondary outcomes of clinical and/or scientific importance. Be as specific as possible with the metric used (e.g., "% with Beck Depression Score > 10" rather than just "depression"). Examples: Outcome Name: all-cause mortality, Timepoint: 6 months, 1 year; or Outcome Name: Mean glycosylated hemoglobin A1C, Timepoint: 4 and 8 weeks

Non-drug Trials Examples

Here are some examples of non-drug trials which apply the WHO Minimum 20 Items Trial Registration Data Set. These examples refer to trials dealing with procedures, behavioral treatments, devices, or process-of-care changes.

A. **Early trials (Phase 1 and Phase 2)**

Non-exhaustive List

1 A randomised controlled trial of an intervention to improve communication with patients suffering acute chest pain: click here

2. The prevention of developmental and behavioral problems of very preterm infants and parental stress through the use of development care: an intervention program for infants and parents: click here

3. New Technologies for Cervical Cancer screening: click here

4 A Randomised Controlled Trial of goal setting and pacing for cardiac patients not suitable for group based cardiac rehabilitation: click here

5 Group Counseling for Smoking Cessation: click here

6. Cell Repair in Heart Failure: click here

7 Phase 1 Study of the Biologic Lung Volume Reduction (BLVR) System in Patients With Advanced Upper Lobe Predominant Emphysema: click here

B. **Phase 3 and above**
Non-exhaustive List

1. Feasibility study of the effect of price discounts and nutrition education on food purchases in supermarkets: click here

2 Domiciliary versus centre-based rehabilitation of older community dwellers: Randomised trial with economic evaluation: click here

3 Cluster-randomised trial of general practitioners to evaluate the effects of education versus no specific education about depression and self-harm behaviour in later life: click here

4. Promoting Physical Activity in Later Life: Impact on Memory and Mood: click here

5. The effects of Tea Tree oil on acne: click here

6 House dust mite allergen avoidance and omega 3 fatty acid supplementation to reduce the incidence of asthma in children with a family history click here

C. **Other non-randomised trials**
Non-exhaustive List

1. Evaluation of an interdisciplinary assessment service to evaluate new prosthetic prescriptions for trauma related trans-femoral amputees: click here

2 Study of Decision Making in Patients Participating in Phase I Clinical Trials: click here

3. Evaluating Patient Participation in Phase I Clinical Trials: click here